International Vaccine Technology Workshop

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Factors to consider in determining what technologies are best-suited for individual nations' short, mid and long-term goals

Infrastructure Limitations and Solutions

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Infrastructure

Equipment Facilities

You need a building in which to work and equipment to execute the technologies

Systems and Processes

- QA
- Regulatory
- Tech Transfer
- Project Mngt
- Engineering
- etc

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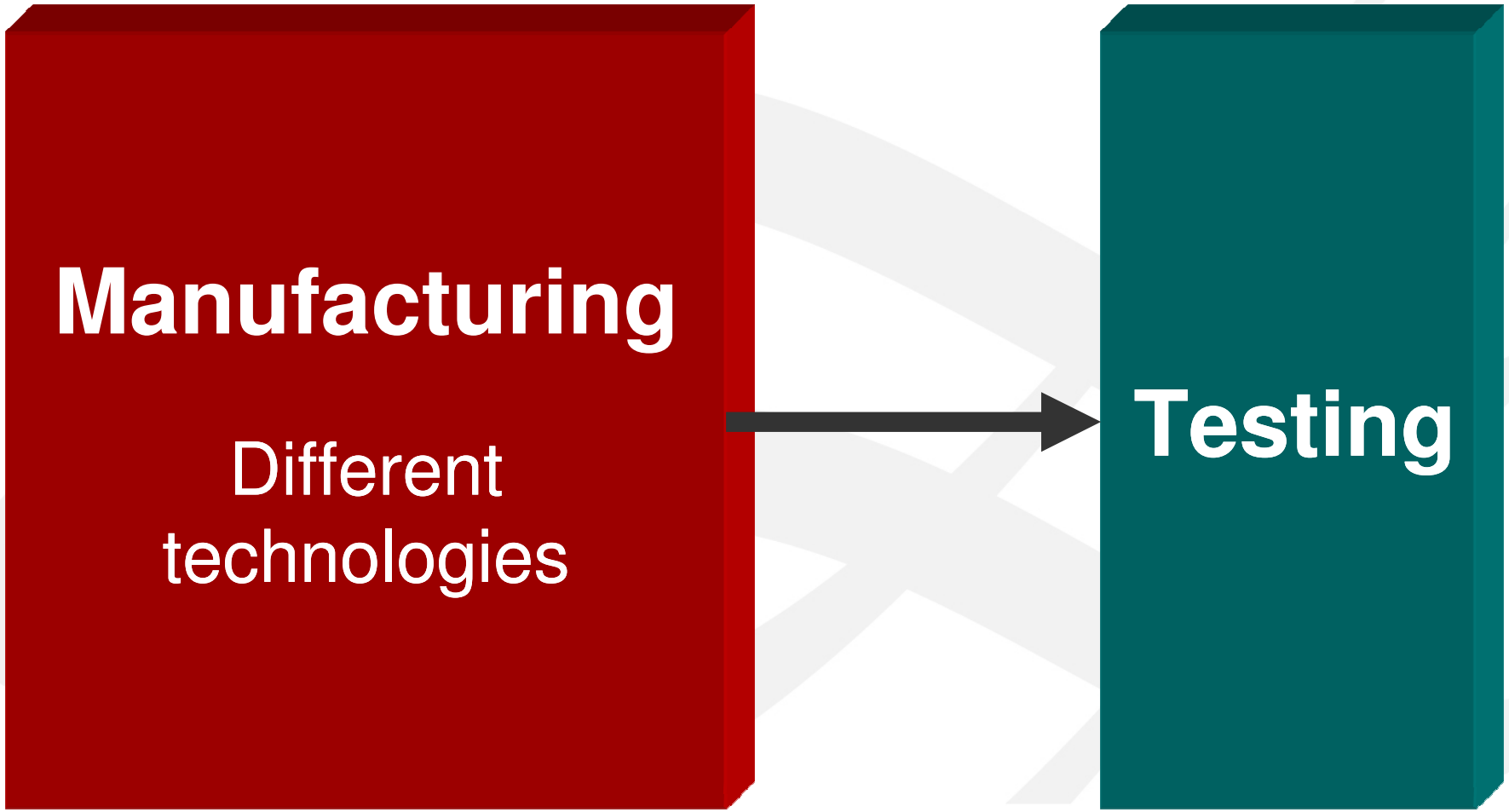
Technologies



Vaccine Manufacture

is a multi-step process

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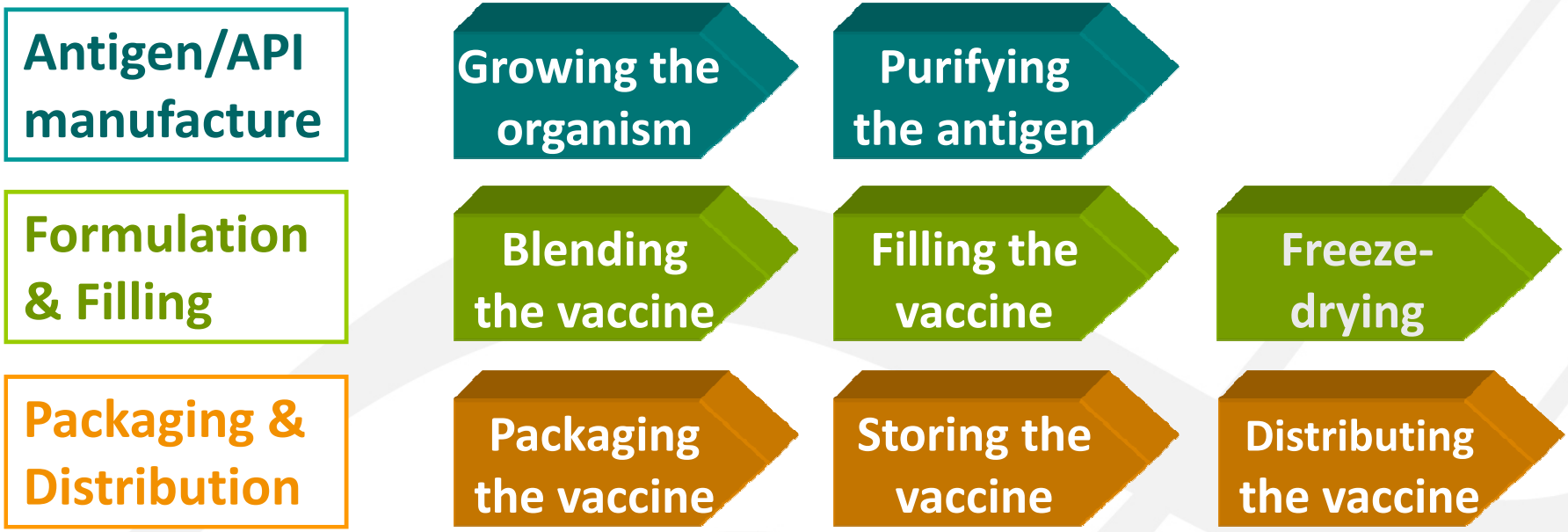

…and each step has specific equipment and facility requirements

Antigen Manufacture

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Examples of factors to consider

- Microbial fermentation,
- Cell culture
- Egg based
- Biosafety level requirements
- Scale
- Inoculum train

- Number of purification steps
- Number of rooms required
- Scale and volumes
- Special considerations:
  e.g. high volumes of flammable liquids

Formulation & Filling

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Examples of factors to consider

- Scale and Volumes
- Adjuvants
- Buffers
- Temperature requirements
- Live or killed vaccine

- Vials / syringes
- Fill volumes (single / multi)
- Scale
- Live or killed vaccine

- Freeze drying
- Volumes /scale
- Live or killed vaccine

Packaging & Distribution

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Examples of factors to consider

- Inspection
- Oral vs injectable vs…
- Vials / Syringes
- Labelling
- Units per carton
- Volumes
- VVMs

- Vials / syringes
- Temperature

- Temperature
- Geography

Testing

Examples of factors to consider

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- Animal testing
- Microbiological testing
- Physico-chemical testing
- Specialized equipment
- Testing frequency

The Approach

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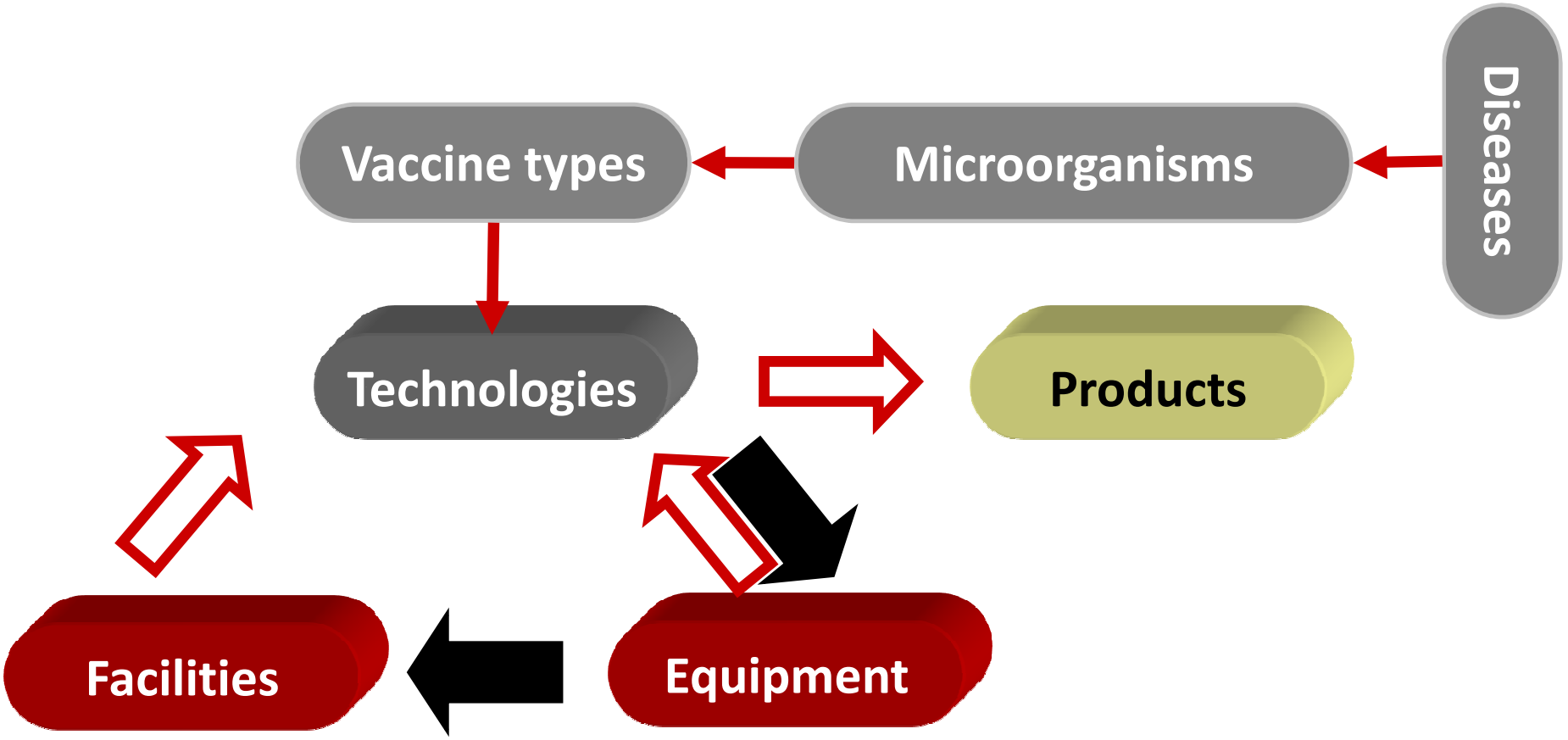
Link between
infrastructure, technology and products



Utility and Services

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- Power
- Compressed air
- Water
- Steam

Capacity Requirements

Flows

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- People
- Product
- Material
- Waste
- Air

Skills and Capacity

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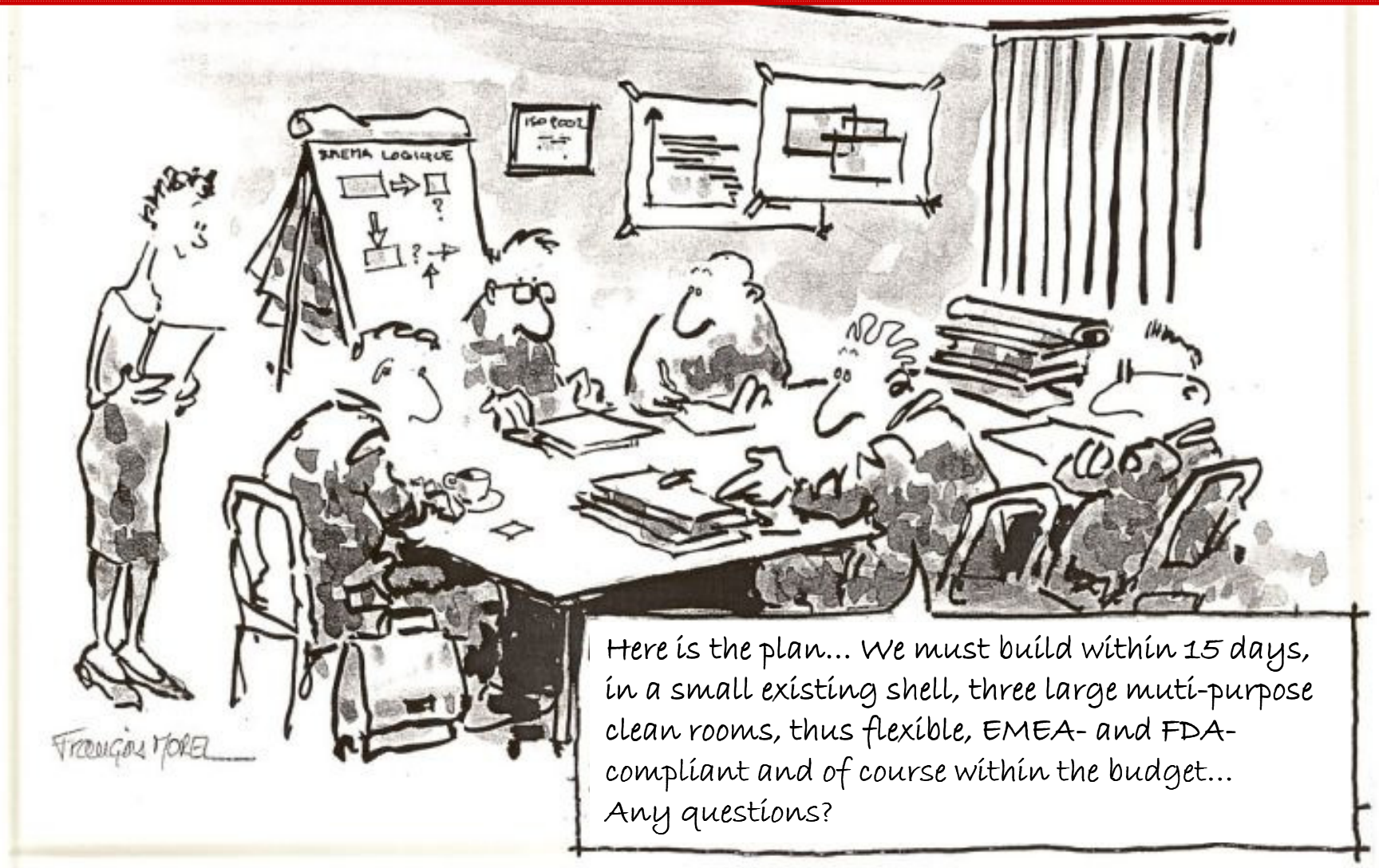
Here is the plan… we must build within 15 days, in a small existing shell, three large multi-purpose clean rooms, thus flexible, EMEA- and FDA-compliant and of course within budget… Any questions?



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Challenges

- Time
- Flexibility
- Regulatory
- Money
- Skills and technical support

Decision to invest in capacity or facility has to be done well in advance – before regulatory decision can be expected

Suggestions for consideration

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- Backward integration strategy
- Employ experts
- Outsource
- Partner
  - **local companies for technical support**
  - **foreign experienced companies for specialized services**
  - **Expert consultants**
  - **Technology transfer donors**
- Establish hubs for transfer of skills for generating equipment specifications and designing facilities
- Single use technology
- Multiproduct facility design (future projections)
- Leverage value - platform approach
- Political support

Come to terms with...

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- Limitations are a reality
- It is not cheap
- It takes time
- Requirement for comprehensive skill set
- Settle for tradeoffs

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Thank You

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